

quence. Better alternatives to partial meniscectomy are therefore being sought. Allograft transplantation is a fairly successful alternative. However there is no proof that replacement of the meniscus with an allograft can re-establish some of the important meniscal functions, and thereby prevent or reduce the development of osteoarthritis secondary to meniscectomy (Messner, K. and Gao, J. 1998 The menisci of the knee joint. Anatomical and functional characteristics, and a rationale for clinical treatment. *Journal of Anatomy*, 193:161-178). The major problems are the lack of remodelling of the graft resulting in inferior structural, biochemical and mechanical properties and insufficient fixation to bone. Further disadvantages include the shortage of suitable donors, difficulties with preservation techniques, the possible transfer of diseases, difficulty in shaping the implant to fit the donor and possible immunological reactions to the implant (Stone, K. R. *Clin. Sports Med.* 1996, 15, 557-571).

[0012] Total knee replacement cannot be considered as treatment for uncomplicated meniscal injury. Dacron and Teflon meniscal prosthetic components may initiate severe synovial reactions (Cook, J. L., Tomlinson, J. L., Kreeger, J. M., and Cook, C. R. 1999. The American Journal of Sports Medicine 27:658-665 Induction of meniscal regeneration in dogs using a novel biomaterial) while loosening and mechanical failure are a problem (de Groot, J. H. 1995 Doctoral dissertation. University of Gronigen, Summary p 153).

[0013] Partial or total meniscal replacements made from collagen, Teflon fibre, carbon fibre, reinforced polyester, or polyurethane-coated Dacron showed high failure rates resulting from poor fixation, mechanical failure or severe inflammatory response.

[0014] Elastomers based on amphiphilic urethane block copolymers have been suggested for meniscal repair and tested in an animal model. (Heijkants, R. G. J. C. 2004 Polyurethane scaffolds as meniscus reconstruction materials, Ph.D. Thesis, University of Groningen, The Netherlands, MSC Ph.D.-thesis series 2004-09; ISSN: 1570-1530; ISBN: 90 367 2169 5, chapter 10 pp 167-184) These materials are likely to produce less toxic degradation products than Dacron or Teflon. However, the mechanical properties of the polyurethanes tested did not match native meniscus very well and this may help to explain why only poorly orientated collagen was found in the regenerating fibro-cartilage in the implanted devices in place of the well-orientated collagen in normal meniscus. A further potential problem was that the polyurethane materials produced a Stage I inflammatory response (giant cells and some macrophages).

[0015] Recently, tissue engineering strategies for meniscal repair have been suggested including the use of biocompatible grafts as a substrate for regeneration, and cellular supplementation to promote remodeling and healing. Little is known, however, about the contributions of these novel repair strategies to restoration of normal meniscal function. (Setton, L. A., Guilak, F., Hsu, E. W. Vail, T. P. (1999) Biomechanical Factors in Tissue Engineered Meniscal Repair. *Clinical Orthopaedics & Related Research*. (367S) supplement: S254-S272, October 1999).

[0016] U.S. Pat. No. 4,344,193 (Kenny/Dow Chemical) appears to have been the first patent document to disclose the idea of a meniscal prosthesis rather than a total joint replacement endoprostheses. The meniscal prosthesis suggested is of non-reinforced silicone rubber. This material has low biocompatibility and would be likely to trigger a severe synovial reaction.

[0017] U.S. Pat. No. 4,502,161 (Wall) discloses a meniscal prosthesis of silicone rubber, rubber or polytetrafluoroethylene with a reinforcing mesh of stainless steel strands, nylon or a woven fabric embedded within it. The suggested materials have low biocompatibility and would be likely to trigger a severe synovial reaction.

[0018] WO 89/00413 (Stone/Regen Biologics Inc.) discloses a prosthetic meniscus made of a three-dimensional array of collagen type I fibres interconnected via crosslinks consisting of polymerised glycosaminoglycan molecules. In vivo, the matrix has an outer surface contour substantially the same as that of a natural meniscus. The matrix provides a partially resorbable scaffold adapted for the ingrowth of meniscal fibrochondrocytes. Whilst the constructs may have a defined shape and size, the mechanical properties—in particular the compressive modulus—do not approach that of cartilage.

[0019] U.S. Pat. No. 4,919,667 (Richmond/Stryker) discloses a meniscal prosthesis constructed from polyester bonded with polyurethane. The polyester is arranged as a felt in one or more intermediate layers sandwiched between a woven cloth top and bottom layer also of polyester. The polyester and polyurethane are likely to be more biocompatible than the materials of U.S. Pat. No. 4,502,161.

[0020] U.S. Pat. No. 6,306,169 (Lee) discloses an implant consisting of a porous macrostructure the pores of which are filled up with a hydrated gel. The macrostructure is made of a bioresorbable polymer (collagen, gelatin, poly-L-lactic acid, polycaprolactone, polyhydroxybutyrate, or polyanhydrides) and the non-porous, hydrated gel consists of alginate, agarose, carrageenans, glycosaminoglycans, proteoglycans, polyethylene oxide or collagen monomers. This structure improves on the mechanical properties of the constructs of WO 89/00413, but still struggles to reach those of cartilage.

[0021] U.S. Pat. No. 6,514,515 and U.S. Pat. No. 6,867,247 (Williams) discloses the use of a bioresorbable and biocompatible polymer of polyhydroxyalkanoate for tissue repair. Such polymers may be tuned to have specific mechanical properties.

[0022] U.S. Pat. No. 6,679,914 (Gabbay) discloses a meniscal prosthesis comprising a plurality of superimposed sheets of animal pericardium cross-linked by an aldehyde.

[0023] WO 00/72782 (Wolowacz/Smith & Nephew) discloses a biocompatible, resorbable implantable material for total replacement or reinforcement of connective tissue consisting of a flexible tape containing aligned fibres. The application mentions the use of a hydrogel as a 'carrier medium' by means of which cells are incorporated into the material.

[0024] The structure and function of the intervertebral disc has been reviewed by Matcher, S J, Winlove, C P and Gangnus, S V., (2004) in their article, "The collagen structure of bovine intervertebral disc studied using polarization-sensitive optical coherence tomography" published in *Physics in Medicine and Biology*, volume 49 pages 1295-1306. A disc comprises an inner region, the nucleus pulposus surrounded by the annulus fibrosus. The inner nucleus pulposus is a visco-elastic gel constructed from proteoglycans trapped in a disordered network of fine type-II collagen fibrils. In contrast, the outer annulus fibrosus consists of axially concentric lamellae, constructed from larger fibrils of type I collagen and a considerably lower concentration of proteoglycans. The fibres run parallel to each other within each lamella of the annulus fibrosus but at a constant angle to the axis of the disc. This angle alternates from lamella to lamella to give a trellis-